

WE CLAIM:

- ① A method for evaluating the clinical utility of target molecules comprising the steps of:
- A. providing a large quantity of different tissue samples;
  - B. providing a target molecule;
  - C. providing a stain that specifically binds to said target molecule *in situ*;
  - D. applying, in a high-throughput manner, said stain to said tissue samples; and
  - E. determining the extent to which said stain has bound to said target molecule in said tissue samples.
2. The method according to claim 1 wherein said high-throughput manner comprises the use of a tissue microarray.
3. The method according to claim 1 wherein said high-throughput manner comprises the use of an automated stainer.
4. The method according to claim 1 wherein said high-throughput manner comprises the use of both a tissue microarray and an automated stainer.
5. The method according to claim 1 wherein said clinical utility comprises utility as a diagnostic marker for determining whether a patient will respond to a particular therapy.
6. The method according to claim 5 wherein said therapy is a drug that interacts with said target.
7. The method according to claim 1 wherein said clinical utility comprises validation that target is relevant in a particular tissue for purposes of treatment selection.

8. The method of claim 1 wherein a plurality of target molecules are provided from a plurality of sources.

9. A method for determining the clinical utility of target molecules from a plurality of sources comprising the steps of:

- A. providing a large quantity of different tissue samples;
- B. providing a plurality of target molecules from a plurality of sources;
- C. providing a stain that specifically binds to said target molecule;
- D. applying said stain to said tissue samples; and
- E. determining the extent to which said stain has bound to said target molecule in said tissue samples.

10. A method for determining whether a target molecule has clinical utility comprising the steps of:

- A. Providing a stain that specifically binds to a target molecule in said tissue sample, wherein said target molecule was identified using an array;
- B. Providing an instrument for automatically applying said stain to said tissue sample;
- C. Applying said stain to said tissue sample using said instrument; and
- D. Determining the extent to which said stain has bound to said target molecule.

11. The method according to claim 10 wherein said array comprises a plurality of different oligonucleotides mounted to a solid support.

12. The method according to claim 10 wherein said array comprises a plurality of different tissue samples mounted to a solid support.

13. The method according to claim 10 wherein said method is high-throughput.

14. The method according to claim 10 wherein said instrument comprises:  
a first heater for heating a first slide; and  
a second heater for heating a second slide;  
wherein said first heater is capable of heating said first slide to a temperature different from the temperature of said second slide.
15. The apparatus of claim 14 wherein said first and second heaters are mounted to a carousel.
16. The apparatus of claim 14 and further comprising means for monitoring and controlling the temperature of said first and second heaters.
17. A tissue microarray comprising:  
A. a solid surface;  
B. a plurality of different tissues mounted to said solid surface; and  
C. a machine readable marking for identifying how said tissues are to be treated by said machine.
18. The tissue microarray according to claim 17 wherein said machine readable marking is a bar code label.
19. The tissue microarray according to claim 17 wherein said solid surface is a glass microscope slide.
20. The tissue microarray according to claim 17 wherein said treatment comprises automated staining of said tissues by said machine.